UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,409	01/18/2002	Susumu Maruo	Q68143	2146

23373 7590 07/27/2004

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,409	MARUO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (2 months-granted), the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the Amendment and Applicant's Arguments/Remarks, all filed 05/05/04 is acknowledged.

Claims 1, 4-8 and 11-12 are pending. Claims 1, 4-8, 11 and 12 have been amended. Claims 2-3 and 9-10 have been cancelled. Claims 1, 4-8 and 11-12 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (US Pat. No. 5, 045,553) in view of Woo *et al.* (US Pat. No. 6,455,067 B1).

Ueda *et al.* teach a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda et al. teach that the pharmaceutical composition can be administered in various dosage forms. When the composition is in the form of a patch, the composition is spread over a support member (col. 3, lines 43-55). The composition may also be made up into ointments, such as Macrogol ointments, FAPG ointments, hydrophilic ointments, absorptive ointments, Carbopol gel ointments, etc (col. 3, lines 64-68). It is also possible to fill the composition in an appropriate container (to prevent adherence to clothes) and attach the container to the skin so that the composition can come into contact therewith or to coat a support member (as in tape preparations) with the composition to a certain thickness and apply the whole to the skin (col. 4, lines 9).

Furthermore, the composition can be made up into patches, for example, by spreading the composition over an appropriate support member (i.e., made of aluminum), and if necessary sealing with an absorption promoter film such as ethylene-vinyl acetate copolymer film (col. 4, lines 10-20). The Examples on cols. 7-9 further demonstrates the use of patch preparations comprising a support member and a gel (ointment) in various percentages, which read on the applicant's instantly claimed ranges.

Ueda *et al.* while teaching a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12), do not explicitly teach the degree of water vapor permeability of the support. It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable amounts or ranges of water vapor permeability through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Ueda *et al.* are lacking in the sense that they do not explicitly teach a support material comprising a copolymer of vinyl acetate and acrylic acid.

Woo *et al.* teach a transdermal patch comprising a synthetic polymer of *polyvinyl acetate-acrylic acid copolymer* used for strengthening the water retention, the processing and plasticity of the patch. The patch also contains various ointments, gels and support materials made of fabric cloth. The patch provides excellent dermal absorption and good skin adhesion without skin irritation (see reference column 6, lines 5-19); (col. 5, lines 3-13); (col. 6, lines 25-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined reference teachings of Woo *et al.* within Ueda *et al.* for the teaching of vinyl acetate/acrylic acid copolymers because Woo *et al.* teach a transdermal patch comprising a synthetic polymer of polyvinyl acetate-acrylic acid copolymer which functions to provide strengthening of water retention, processing and plasticity of the patch without influencing the effects of the patch and similarly Ueda *et al.* teach a patch preparation comprising absorption promoting films such as ethylene-vinyl acetate copolymer film, support materials, ointments and gels contained in the patch. The expected result would be an effective skin patch with improved strengthening, processing and plasticizing capabilities.

Response to Arguments

Applicant's arguments filed 05/05/04 have been fully considered but they are not persuasive.

The Applicant specifically argued, "Independent claims 1 and 8 have been amended to recite that the support...comprises a copolymer of vinyl acetate and acrylic acid, wherein the copolymer is obtained by copolymerizing a vinyl acetate...and the copolymer is cross-linked. Ueda et al. does not disclose or suggest the use of a copolymer as the support material."

These arguments have been thoroughly considered, but were not found to be persuasive. Instant pending claims 1, 4-8 and 11-12 have now been rejected under 35 U.S.C. §103(a) over Ueda et al. ('553) in view of Woo et al. ('067). Ueda et al. teach a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda *et al.* do not explicitly teach the use of vinyl acetate-acrylic acid copolymer.

Woo *et al.* is relied upon for their explicit teaching of a transdermal patch that comprises synthetic polymer of polyvinyl acetate-acrylic acid copolymer, whereby the polyvinyl acetate-acrylic acid copolymer is used for its strengthening of water retention, processing and plasticity abilities, without influencing the effect of the patch.

The patch offers good skin adhesion without causing skin irritation to the user. Additional support materials include fabric cloth, used as the supporter (see col. 5, line 3 through col. 6, line 37).

With regards to the instant support thickness, percent modulus and water vapor permeability, it is the Examiner's position that no criticality is seen in the instantly claimed amounts or percentage ranges, since one of ordinary skill in this art would be capable of determining suitable amounts through the use of routine or manipulative experimentation to obtain the best possible outcome, as these are all variable parameters.

Ample motivation is provided by the prior art to obtain a patch preparation that offers excellent absorption, greater strength, improved processing and plasticity abilities. No significant distinction has been observed between the instant invention and the prior art since the prior art teaches a similar composition comprising similar ingredients, used for the same field of endeavor and to solve the same problems as that desired by Applicant. Hence, the instant invention is rendered *prima facie* obvious over the prior art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
July 26, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600